

application must be complete and must not refer to any accompanying application for required information.

**§ 1309.34 Acceptance for filing; defective applications.**

(a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days of receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time.

(b) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1309.35 and has no bearing on whether the application will be granted.

**§ 1309.35 Additional information.**

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

**§ 1309.36 Amendments to and withdrawals of applications.**

(a) An application may be amended or withdrawn without permission of the Administration at any time before the date on which the applicant receives an order to show cause pursuant to § 1309.46. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, including a request that the applicant submit the required fee, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

**ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION**

**§ 1309.41 Administrative review generally.**

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of Section 303 of the Act (21 U.S.C. 823) have been met by the applicant.

**§ 1309.42 Certificate of registration; denial of registration.**

(a) The Administrator shall issue a Certificate of Registration (DEA Form 511) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of section 303 of the Act (21 U.S.C. 823). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1309.51.

(b) The Certificate of Registration (DEA Form 511) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the amount of fee paid, and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by

## § 1309.43

any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to List I chemicals or controlled substances.

### § 1309.43 Suspension or revocation of registration.

(a) The Administrator may suspend any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time he determines.

(b) The Administrator may revoke any registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(c) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to Section 1309.46 and, if requested by the registrant, shall hold a hearing pursuant to Section 1309.51. Notwithstanding the requirements of this Section, however, the Administrator may suspend any registration pending a final order pursuant to §1309.44.

(d) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all List I chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all such List I chemicals in his or her possession under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(e) In the event that revocation or suspension is limited to a particular chemical or chemicals, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revok-

## 21 CFR Ch. II (4-1-02 Edition)

ing or suspending registration with respect to a particular chemical or chemicals, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

[60 FR 32454, June 22, 1995, as amended at 62 FR 5916, Feb. 10, 1997]

### § 1309.44 Suspension of registration pending final order.

(a) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he shall serve with the order to show cause pursuant to §1309.46 an order of immediate suspension that shall contain a statement of his findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of immediate suspension, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).